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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,412	04/15/2004	Terry Thomas	7771-110	6483

1059 7590 06/14/2005

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/824,412

Applicant(s)

THOMAS ET AL.

Examiner

David A. Saunders, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Amendment of 4/15/04 has been entered. Claims 1-3 are pending. Claims 1-12 are under examination.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either on an application data sheet or supplemental oath or declaration.

Furthermore, the signatures are not dated.

The disclosure is objected to because of the following informalities:

At page 1, in the paragraph showing continuity data, the Pat. No. for allowed application 09/822,823 must be provided.

Appropriate correction is required.

Prior to examination of the claims over the prior art the effective filing date of each claim must be established.

Claims 1-3, 7, 9 and 11-12 are granted benefit of the filing date of grand-parent application 09/579,463 (See original claims 1-3, 26, 28 and 33 therein; see disclosure of anti-glycophorin-A antibodies throughout).

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Claims 1-3 and 11- 12 are also granted benefit of the filing date of the earliest provisional application 60/136, 770 (see original claims 7-9 and 20 therein; see disclosure of anti-glycophorin-A antibodies throughout).

Claims 4-6, 8 and 10 are given benefit of the filing date of parent application 09/822,823. Claims 4 and 6 are only given benefit of this filing date because, while these parallel original claims 26 and 28 of the '463 application, they are broader by virtue of not limiting the cells to tumor cells.

Claims 5 and 8 are only granted benefit of this filing date, because these claims relate to page 14, lines 10-17; page 21, lines 5-12 and Table 3; none of this disclosure appears in grand-parent '463.

Claim 10 is only given benefit of this filing date because, while it parallels original claim 27 and of the '463 application, it is broader by virtue of reciting "and/or" rather than "and", before the last recited CD antigen.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

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Claims 1-3, 7, 9 and 12 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3, 26, 28 and 33, respectively, of prior U.S. Patent No. 6,448,075. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4-6, 8 and 10-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 26-27 and 29 of U.S. Patent No. 6,448,075. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 4 parallels the recitation of issued claim 26, but for the fact that the instant claim recites "non-hematopoietic cells" where the issued claim recites "non- hematopoietic tumor cells". Since the former encompasses the latter, a disclaimer is required to assure continued common ownership of the two sets of claims.

Instant claims 6 and 10 parallel the recitations of issued claims 27 and 29, respectively; however, the instant claims recite "and/or" while the issued claims simply recite "and" in setting off the last recited member of each group of antibodies. Since "and/or" clearly encompasses

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“and”, the instant and issued claims have common embodiments, and a disclaimer is required to assure continued common ownership of the two sets of claims.

Instant claim 11 parallels no issued claim in its recitation; however, the embodiment wherein antibody (b) of claim 1 is one that binds glycophorin-A on erythrocytes would be clearly encompassed by issued claim 1, because anti-glycophorin-A is disclosed and exemplified through out the specification of Pat. '075 as a preferred embodiment of antibody (b). A disclaimer is required to assure continued common ownership of the two sets of claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-6, 8 and 10 are rejected under 35 U.S.C. 102 (b) as being anticipated by Peters et al (Proceed. Amer. Assoc. Cancer Res., Vol. 41, p. 589, March 2000).

As noted supra claims 4-6, 8 and 10 only have benefit of the 4/2/01 filing date of parent application 09.822823. Since this date is more than one year after March 2000, the rejection under 102(b) is proper.

Peters et al teach all aspects of the instant immunosetting method involving negative selection, including the removal of cells having the CD antigens recited in claims 4-6, 8 and 10. Peters et al teach the enrichment of epithelial tumor cells which are a type of non-hematopoietic cell.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al (FASEB Journal 2000) in view of Thomas et al (6,117,985).

The Peters et al reference pre-dates the filing date of parent 09/579,463; however it post-dates the filing date of provisional application 60/136,770. This reference is therefore not applied against instant claims 1-3 and 11-12.

Peters et al teach the basic aspects of the instant immunorsetting method, and they teach bispecific antibody reagents for this method. Peters et al do not show unwanted or undesired cells having the CD antigens recited in claims 4-10.

Thomas et al disclose (col. 6, Lines 48-59) that it would be desirable to remove cells containing CD45 and CD66b, among other antigens and optionally to remove cells containing CD36. Thus all CD antigens recited in claims 4-10 are shown to be on undesired cells, when one uses a negative selection method to enrich non-hematopoietic tumor cells.

Regarding claim 9, note Thomas et al col. 14, lines 57-62 teaching epithelial tumor cells.

It would have been obvious to use the immunorsetting reagents and method taught by Peters et al to enrich non-hematopoietic tumor cells via negative selection using antibodies to the CD antigen markers taught by Thomas et al, in conjunction with

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an antibody to the glycophorin - A (erythrocyte antigen) taught by Thomas et al. By using a cocktail of antibodies bispecific for glycophorin-A and each of the CD antigens taught by Thomas et al, one would have expected to effectively remove cells with all of the antigens listed by Thomas et al (col. 6, lines 50-51) by the formation of immunorosettes like those formed in the method of Peters et al. Motivation to do so comes from the fact that Peters et al teach that one can obtain cells with a purity equal to that obtained by more complicated immunomagnetic techniques (note that the method of Thomas et al would require complicated separation steps when using magnetic colloids, as shown in Fig. 1).

Regarding the IDS submitted 8/10/04, the web site, listed as item 8, has not been searched. The corresponding technical bulletin has been viewed, as it exists in the record of parent 09/822,823.

The Peters et al reference, listed as item 7, has been lined out because there is no copy of this in any related application file, or imaged record thereof. This reference is cited on attached Form 892, and a copy is supplied. In this manner there will be an imaged copy of the reference in the file record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 6/10/05 DAS

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182/644